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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,031	02/20/2004	Cory Schaffhausen	5490-000359	1684

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,031

Applicant(s)

SCHAFFHAUSEN, CORY

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 20-32 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2-20-04, 8-23-05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment received on 7 September 2006.

Election/Restrictions

2. Applicant's election with traverse of invention 1 (method of repairing a tear in body tissue) in the reply filed on 7 September 2006 is acknowledged. The traversal is on the ground(s) that the search for inventions 1 and 2 is essentially the same. This is not found persuasive because the device of invention 2 can be used to perform various procedures, including connecting a hollow body organ to the abdominal wall during a percutaneous endoscopic gastronomy, therefore increasing the field of search beyond that of only invention 1.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claim 26 is objected to because of the following informalities: the word "portion" is incorrectly spelled as "potion" in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claim 1-7 and 20-32 is rejected under 35 U.S.C. 102(b) as being anticipated by Sikora et al. (US Patent Application 2002/0019649).**

6. Sikora'649 discloses a method for closing a tissue wound that includes inserting a needle (1070) containing a retaining head (1012) from a first insertion position (1060a) on a first outer surface of the body tissue, through the tear (1052) and to a second outer surface (1058) of the body tissue; ejecting the retaining head (1012) from the needle (1070) wherein the retaining head (1012) grasps the second outer surface (1058) in an engaged position (paragraph [0152]); advancing an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines 1-2) from a second insertion position (1060b) on first outer surface of the body to a position through a portion of the tear (1052) (paragraph [0153]), said anchor (1014) coupled to the retaining head by a flexible member that extends a distance along the first outer surface of the body tissue from said first insertion position to said second insertion position (see Figure 1, element 10b).

7. Regarding Claim 2, Sikora'649 discloses a method that includes ejecting the retaining head (1012) further includes advancing a plunger within the needle (1070) towards a distal opening of the needle, deploys the retaining head (1012) through the

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distal opening of the needle (1070), and removing the needle from the body tissue at opening first insertion portion (1060a) (see paragraph [0152]).

8. Regarding Claim 4, Sikora'649 discloses that advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance towards the distal end in order to advance anchor (1014) to a desired location (paragraph [0153]).

9. Regarding Claim 3 and 5, Sikora'649 discloses a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Regarding Claim 6, Sikora'649 discloses locating the distal end of the hollow tube (1070) a predetermined offset position (1060b) a predetermined offset position from the said first insertion position (1060a) and advancing the anchor to the desired location provides a taught flexible member between the first and second insertion positions (paragraph [0153]).

10. Regarding Claim 7, Sikora'649 discloses that ejecting the retaining head is performed simultaneously with advancing the anchor (paragraph [0150] and [151]).

11. Regarding Claim 20, Sikora'649 discloses a method of repairing a tear in a body tissue that includes a passing a needle (1070) from a first portion of the body tissue through the tear (1052) and to an outer surface of the body tissue (1058); ejecting a retaining head (1012) from the needle (1070) so that the retaining head (1012) lies against the outer surface (1058) in an engaged position (paragraph [0152]); and inserting an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines

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1-2) by a flexible member (1016) from a first portion through the tear to a desired location (paragraph [0153]).

12. Regarding Claim 21, Sikora'649 discloses inserting the anchor (1014) to the desired location wherein the flexible member (1016) extends a distance along the first portion of the body tissue (see Figure 20, paragraph [0152] and [0153]).

13. Regarding Claim 22, Sikora'649 discloses that the flexible member (1016) is taught between the anchor (1014) and the retaining head (1012) (paragraph [0153]).

14. Regarding Claim 23, Sikora'649 discloses advancing a plunger (1080) within the needle (1070) towards a distal opening of the needle (direction A, Figure 20), deploying the retaining head (1012) from the distal opening and removing the needle (1070) from the body tissue (paragraph [0152]).

15. Regarding Claim 24, Sikora'649 discloses a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

16. Regarding Claim 25, Sikora'649 discloses that advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance t to advance anchor (1014) to a desired location (paragraph [0153]).

17. Regarding Claim 26, Sikora'649 discloses that the first portion of the body tissue is a first outer surface of the meniscus (paragraph [0151], Figure 20).

18. Regarding Claim 27, Sikora'649 discloses a method of repairing a tear in a meniscus that includes inserting a cannulated piercing member (1070) containing a retaining head (1012) therein from a first insertion position on a first outer surface of the

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meniscus through the tear (1052) and to a second outer surface of the meniscus (1058) (paragraph [0151]), where the retaining head (1012) has a longitudinal body and is positioned longitudinally within the cannulated piercing member (1070) (paragraph [0015]); ejecting the retaining head (1012) from the piercing member (1070) so that the head engages with the second outer surface (1058) (paragraph [0152]); and advancing an anchor (1014) coupled to retaining head (1012) from a second insertion position (1060b) on the first outer surface of the meniscus to an implanted position (at side 1058), wherein when in the implanted position (at side 1058) the anchor passes through a portion of the tear (1052); further the anchor (1014) is coupled to the retaining head (1012) (paragraph [0005]) that extends a distance along the first outer surface of the meniscus (Figure 20, paragraph [0153]).

19. Regarding Claim 28, Sikora'649 discloses that ejecting the retaining head (1012) from the piercing member (1070) includes advancing a plunger (1080) within the piercing member (1070) towards a distal opening (1074) of the piercing member (1070); deploying the retaining head from the distal opening (1074) and removing the piercing member from the meniscus at the first insertion position (paragraph [0152]).

20. Regarding Claim 29, Sikora'649 discloses a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

21. Regarding Claim 30, Sikora'649 discloses advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance towards the distal

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end in order to advance anchor (1014) to a desired location in the meniscus (paragraph [0153]).

22. Regarding Claim 31, Sikora'649 discloses locating the distal end of the hollow tube (1070) a predetermined offset position (1060b) a predetermined offset position from the said first insertion position (1060a) and advancing the anchor to the desired location provides a taught flexible member between the first and second insertion positions to close the tear (paragraph [0153]).

23. Regarding Claim 32, Sikora'649 discloses that ejecting the retaining head is performed simultaneously with advancing the anchor (paragraph [0150] and [151]).

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allen, et al. (US Patent 5,467,786); Albright, et al. (US Patent 4,493,323); Fallin, et al. (US Patent 6,972,027).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER